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EXAMINER

NAFF, DAVID M

ART UNIT

PAPER NUMBER

1651

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*CH*

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/068945

Applicant(s)

GRIFFITH JAL

Examiner

HARR

Group Art Unit

1651

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

## Status

- ☒ Responsive to communication(s) filed on 2/19/03
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- ☒ Claim(s) 25-52 is/are pending in the application.
- ☐ Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- ☒ Claim(s) 27 + 44-52 is/are allowed.
- ☒ Claim(s) 25, 26 + 28-43 is/are rejected.
- ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- ☐ Claim(s) \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
  - ☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been received.
  - ☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_
  - ☐ received in this national stage application from the International Bureau (PCT Rule 1.7.2(a)).

\*Certified copies not received: \_\_\_\_\_

## Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_
- ☒ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Interview Summary, PTO-413
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Other \_\_\_\_\_

Office Action Summary

In view of the appeal brief filed on 2/19/03, PROSECUTION IS HEREBY REOPENED. New grounds of rejection are set forth below.

To avoid abandonment of the application, appellant must exercise one of the following two options:

5 (1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,

(2) request reinstatement of the appeal.

If reinstatement of the appeal is requested, such request must be  
10 accompanied by a supplemental appeal brief, but no new amendments, affidavits (37 CFR 1.130, 1.131 or 1.132) or other evidence are permitted. See 37 CFR 1.193(b)(2).

Claims examined on the merits are 25-52 which are all claims in the application.

15 The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

***Claim Rejections - 35 USC § 112***

Claims 35 and 37-43 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and  
20 distinctly claim the subject matter which applicant regards as the invention.

The claims are confusing and unclear in that it is uncertain as to whether claim 35 is claiming the hydrogel in anatomic form after it has been produced by hardening the polymer, or is claiming the hydrogel in  
25 anatomic form as a form the polymer is capable of hardening to produce.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

5       A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10       Claims 35, 36, 41 and 42 are rejected under 35 U.S.C. 102(b) as being anticipated by Nevo et al (4,642,120).

      Claims 36, 41 and 42 are drawn to an implant that is a cell-polymeric composition for introducing cells into an animal to form tissue comprising dissociated cells and a biodegradable, biocompatible natural  
15 or synthetic organic polymer that hardens into a three-dimensional open-lattice structure which entraps water molecules to form a hydrogel, and being suitable for implantation into an animal before hardening. In claims 35, 41 and 42, the polymer is capable of hardening to form a hydrogel construct having a desired anatomic shape.

20       Nevo et al disclose forming a mixture containing fibrinogen and chondrocytes or mesenchyme cells that gels in the presence of thrombin to form a gel containing cells for implanting to repair cartilage and bone (col 1, lines 60-65). When slow gel formation is desired, less thrombin is used (col 2, lines 44-47).

25       The fibrinogen in the mixture of Nevo et al is a protein which is a natural organic polymer within the scope of the claims, and when the mixture gels it inherently hardens to form a three-dimensional open-

lattice structure which entraps water molecules to form a hydrogel. The mixture is inherently suitable for implantation into an animal before hardening since gel formation is slow when less thrombin is used. Additionally, the mixture of fibrinogen and cells is inherently capable  
5 of forming a hydrogel having a desired anatomic shape.

The mixture containing cells and fibrinogen disclosed by Nevo et al is a cell-polymeric composition that is the same as presently claimed.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35  
10 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

15 (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 35-41 are rejected under 35 U.S.C. 102(e) as being  
20 anticipated by Schlameus et al (5,294,446).

The invention is described above.

Schlameus et al disclose dispersing osteoprogenitor cells in a solution of sodium alginate (col 4, lines 32-34), and subsequently gelling the alginate with calcium chloride to form an alginate gel in the  
25 form of microcapsules containing the cells for implanting to regenerate tissue to promote healing.

The alginate is inherently a natural polymer that can harden by gelling to form a three-dimensional open-lattice structure which entraps water molecules to form a hydrogel. The alginate solution containing

dispersed cells is inherently suitable for implantation into an animal before hardening, and is inherently capable of hardening to form an anatomic shape.

The alginate solution containing dispersed cells of Schlameus et al  
5 is the same as the cell-polymeric composition presently claimed.

***Claim Rejections - 35 USC § 103***

Claim 43 is rejected under 35 U.S.C. 103(a) as being unpatentable over Nevo et al in view of Itay (4,904,259).

Nevo et al is described above.

10 The claim requires the cells to be osteoblasts.

Itay discloses using chondrocytes as cartilage cells or osteoblasts as bone forming cells (col 1, lines 29-31) in a mixture of fibrinogen and cells as disclosed by Nevo et al that is gelled to form an implant for bone or cartilage repair.

15 It would have been obvious to use osteoblasts as bone forming cells in the mixture of fibrinogen and cells disclosed by Nevo et al when bone formation is desired.

***Claim Rejections - 35 USC § 103***

Claims 42 and 43 are rejected under 35 U.S.C. 103(a) as being  
20 unpatentable over Schlameus et al in view of Itay.

Schlameus et al and Itay are described above.

The claims require the cells to be chondrocytes or osteoblasts.

It would have been obvious to use chondrocytes or osteoblasts as the cells dispersed in the alginate solution of Schlameus et al as suggested  
25 by Itay when cartilage or bone is desired to be formed.

***Claim Rejections - 35 USC § 103***

Claims 37-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nevo et al in view of Schlameus et al.

The claims require the polymer to be selected from polymers that  
5 include alginate.

It would have been obvious to replace using fibrinogen and gelling with thrombin in Nevo et al with using alginate and gelling with calcium chloride as suggested by Schlameus et al using alginate and calcium chloride to form a gel containing cells for implanting since the use of  
10 alginate and gelling with calcium chloride would have been expected to be a functional equivalent of using fibrinogen and gelling with thrombin as disclosed by Nevo et al.

***Claim Rejections - 35 USC § 103***

Claims 25, 26, 32, 33, 35, 41 and 42 are rejected under 35 U.S.C.  
15 103(a) as being unpatentable over Nevo et al in view of Capecchi et al (5,292,514) and Vacanti et al (5,804,178).

Claim 25 requires a method wherein the polymer of the cell-polymeric composition is hardened to a desired anatomic shape and is introduced into an animal.

20 Claim 35 requires an implant wherein the polymer of the cell-polymeric composition hardens into a hydrogel having a desired anatomic structure.

Capecchi et al disclose forming prostheses for implanting by forming a hydrogel (col 5, line 25) into a desired shape for implanting (col 4,

lines 7-10) such as by using a mold to form a curved optic shape to provide a corneal implant (col 12, lines 25-30).

Vacanti et al discloses forming a cell-matrix having a variety of shapes depending on the shape required for implantation and formation of a functional organ equivalent (col 5, lines 25-30). The shape may resemble naturally occurring organs (col 8, lines 4-7).

It would have been obvious to produce the gel of Nevo et al having a desired anatomic shape as suggested by Capecchi et al and Vacanti et al producing a hydrogel prostheses or cell-matrix for implanting having a shape resembling a naturally occurring body part or organ.

***Claim Rejections - 35 USC § 103***

Claims 34 and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to claims 25, 26, 32, 33, 35, 41 and 42 above, and further in view of Itay.

15 The claims require the cells to be osteoblasts.

The references are described above.

For reasons set forth above when applying Italy in combination with Nevo et al, it would have been obvious from Itay to use osteoblasts as the cells of Nevo et al when desiring to form bone.

20 ***Claim Rejections - 35 USC § 103***

Claims 28-31 and 37-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to claims 25, 26, 32, 33, 35, 41 and 42 above, and further in view of Schlameus et al.

The claims require the polymer to be selected from polymers including alginate.



The references are described above.

For reasons set forth above when applying Schlameus et al in combination with Nevo et al, it would have been obvious from Schlameus et al to form the gel of Nevo et al using alginate and calcium chloride in place of using fibrinogen and thrombin.

***Claim Rejections - 35 USC § 103***

Claims 25, 26, 28-32, 35 and 37-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schlameus et al in view of Capecchi et al and Vacanti et al.

10 The invention and references are described above.

When gelling alginate to obtain a gel containing cells in the form of microcapsules for implanting as disclosed by Schlameus et al, it would have been obvious to form the gel having an anatomic shape rather than in the shape of microcapsules as suggested by Capecchi et al and Vacanti et al producing a hydrogel prostheses or cell-matrix having a shape resembling a naturally occurring body part or organ.

***Claim Rejections - 35 USC § 103***

Claims 33, 34, 42 and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to claims 25, 26, 28-32, 35 and 37-41 above, and further in view of Itay.

The claims require the cells to be chondrocytes or osteoblasts.

The references are described above.

It would have been obvious to use chondrocytes or osteoblasts as the cells dispersed in the alginate solution of Schlameus et al as suggested by Itay when cartilage or bone is desired to be formed

claims 27 and 44-52 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David M. Naff whose telephone number is (703) 308-0520. The examiner can normally be reached on  
5 Monday-Thursday and every other Friday from about 8:30 AM to about 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, a message can be left on voice mail.


If attempts to reach the examiner by telephone are unsuccessful, the  
10 examiner's supervisor, Mike Wityshyn, can be reached at telephone number (703) 308-4743.

The fax phone number is (703) 872-9306 before final rejection or (703) 872-9307 after final rejection.

Any inquiry of a general nature or relating to the status of this  
15 application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

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DMN  
5/2/03

  
DAVID M. NAFF  
PRIMARY EXAMINER  
ART UNIT 1651